
Report To:	Safe , Sustainable Communities Committee	Date:	3 May 2011
Report By:	Corporate Director Education and Communities	Report No:	SCS/63/11/AH/MM
Contact Officer:	Martin McNab	Contact No:	714246
Subject:	Official Food and Feed Controls		

1.0 PURPOSE

- 1.1 The purpose of this report is to advise the Committee of the Official Feed and Food Service Plan for 2011/12, to report on the achievements of the service in 2010/11 and to advise the committee of potential challenges facing the service in 2011/12.

2.0 SUMMARY

- 2.1 Councils are required under the Framework Agreement on Official Feed and Food Controls by Local Authorities to publish an annual Service Plan documenting how they will deliver the service.
- 2.1 Authorities were formerly required to seek committee approval for the plan but in recent years there has been flexibility in this requirement as reports were often for noting rather than requiring any actual committee decision.
- 2.2 As there are significant challenges facing the food service in 2011/12 and going forward, it is appropriate to bring the 2011/12 Service Plan (Appendix 1) to the attention of the committee and to advise the committee of the external pressures which might impede the service's ability to meet the aims of the plan.
- 2.3 The principal external pressure which might affect the service's ability to meet the plan is the publication of "E. coli O157: Control of cross-contamination Guidance for food business operators and enforcement authorities" (Appendix 2) by the Food Standards Agency (FSA) in February this year. This has the potential to cause significant additional workload for the service in addition to involving significant costs and upheaval for local food businesses.
- 2.4 A further development of note is the current review into the delivery of official food safety controls in the UK by the Food Standards Agency. This could propose the removal of delivery of such controls from local authorities with implications both for the local accountability of such controls and the sustainability of the more general Environmental Health and Public Health role of local authorities.

3.0 RECOMMENDATIONS

It is recommended that the Committee:-

1. approves the Official Food and Feed Service Plan for 2011/12;
2. note the delivery against the 2010/11 plan;
3. notes the challenges facing the service in 2010/11; and
4. agree to receive an update in due course on both progress in implementing the FSA Guidance on Cross Contamination and developments in the FSA's review of food safety controls.

Albert Henderson
Corporate Director Education and Communities

4.0 BACKGROUND INFORMATION

- 4.1 The Official Feed and Food Controls Service Plan is a requirement of the Framework Agreement on Official Feed and Food Controls by Local Authorities. The Framework Agreement sets out what the Food Standards Agency expects from local authorities in their delivery of official controls on feed and food law. In addition to covering service planning the Framework Agreement also sets out delivery requirements and the monitoring and audit arrangements.
- 4.2 The Food Standards Agency is the UK's Central Competent Authority for Feed and Food Controls; however the bulk of delivery of controls is carried out by local authorities. The Framework Agreement therefore provides a basis for monitoring and audit of local authorities' delivery of these controls by the FSA.
- 4.3 The Service Plan addresses various aspects of service delivery under a number of headings specified by the Food Standards Agency.
- 4.4 Key aspects of the plan include
- * Service Aims and Objectives;
 - * Background;
 - * Service Delivery;
 - * Resources;
 - * Quality Assessment; and
 - * Review.
- 4.5 This report details some of these key aspects together with a review of performance against the 2010/11 plan and highlights some future challenges for the service.

5.0 THE 2011/12 SERVICE PLAN

- 5.1 The 2011/12 Service Plan projects a total of 392 food hygiene inspections and 109 food standards inspections. This is broadly in line with the figures for the 2010/11 plan of 342 and 197 respectively.
- 5.2 The programmed inspection numbers are made on the assumption that the new guidance on cross contamination will not have an effect on the programme. Depending on the interpretation of the guidance there is potential for a large number of premises to migrate to a higher risk rating. This will lead to an increase in the number of inspections required. This can be managed either by an increase in resources to the service or by a change in the frequency of inspection. The latter course would most likely involve reducing the frequency of inspection to those businesses in the lower risk ratings whilst maintaining our programme for higher risk businesses. When the implications of the guidance are clear they will be reported to committee.
- 5.3 A key issue for the Service is the reduction in resources available. An officer retired on the grounds of ill-health in 2010 with the post taken as a saving in December. Whilst we were confident at the time that the workload could be covered it was recognised that there was effectively a serious reduction in the resilience of the Service. Were we to lose any other staff for any reason the programmed workload could not be completed using existing resources. This was seen as a risk at the time; however there were no known external factors likely to lead to a significant change in workload. The impact of the Food Standard Agency guidance was not foreseen as the final document was drastically different in scope and implications from that expected.

6.0 Performance Against The 2010/11 Service Plan

- 6.1 The 2010/11 Service Plan projected a total of 342 programmed food hygiene inspections and 197 programmed food standards inspections. In fact with the launch of the Food Hygiene Information Scheme (FHIS) in Inverclyde, covered in report no. ECP/SCS/MM/09/027 of 27 October 2009, a total of 648 food hygiene visits were carried out. This included revisits and advisory visits. The

number of visits arising from FHS in 2011/12 was expected to reduce, however one possible implication of the FSA's guidance on cross contamination may be an increase in the number of businesses receiving an "Improvement Required" rating and hence an increase in the number of revisits required.

- 6.2 The performance of the food service is measured by two KPIs which are reported to the FSA. The first of these is the percentage of premises "Broadly Compliant" with food law. In Inverclyde this has increased from 85.6% in 2009/10 to a provisional figure of 87.3% in 2010/11. It must be noted however that a strict interpretation of the new FSA guidance could lead to a significant drop in this figure in future.
- 6.3 The second KPI is the percentage of food hygiene interventions due at 1 April achieved. In 2009/10 this stood at 92.4%. The provisional figure for 2010/11 is 95.6% against a performance target of 95%. This target was chosen as the maximum achievable without a significant distortion of the output of the team. One Scottish authority achieved 100% in 2009/10, however to achieve such a target requires all other work regardless of risk or importance to be secondary to its pursuit.

7.0 Implications of the FSA Cross Contamination Guidance

- 7.1 The FSA Guidance on cross contamination (Appendix 2), was published in mid February this year. The guidance is noteworthy for a number of reasons. Firstly the detail of the guidance itself was not consulted upon either with local authorities or with businesses. The guidance was produced in response to demand by enforcers for clarity on the status of "dual use" equipment. The Pennington Report into the South Wales E coli outbreak was extremely critical of the use of a vacuum packing machine by the business at the centre of the outbreak for both raw and cooked meats. The enforcement community sought clarity on whether there were any circumstances in which this might be allowable and "guidance" was promised. There was a general request for comments on the principles of such guidance but no consultation on detail.
- 7.2 The guidance as published is far more wide ranging than was expected, covering control of all cross contamination risks in food businesses handling raw and ready to eat food, and its implications for both the enforcement community and businesses are extremely wide ranging. Effectively the guidance aims for a zero tolerance of any risk of cross contamination of ready to eat food by E. coli O157. The reason for this is that very low numbers of these bacteria have the potential to cause serious illness, particularly in the old and young, including kidney failure and death. On this basis it is hard to disagree with the aim, however the implications are extremely severe and wide ranging for food businesses.
- 7.3 To implement the guidance to the letter will require a virtual complete separation of equipment and staff in businesses handling raw and cooked food. These would include the majority of butchers, hotels, restaurants and takeaways amongst others. In normal circumstances a change in enforcement policy of this magnitude would require at least secondary legislation which would have to be fully consulted on and be subject to a regulatory impact assessment. In publishing this as guidance the FSA has managed to avoid this entirely whilst positioning itself as an organisation as above reproach should there be a future fatal accident inquiry into a death arising from O157. The blame for such an event will potentially rest entirely with any business involved and the relevant enforcement authority which can be criticised for not implementing the guidance in its entirety. To implement the guidance immediately in such a way however will almost inevitably lead to significant numbers of businesses failing and potentially result in serious costs to the Council should enforcement actions based upon the guidance be challenged and not be upheld by the courts. As a minimum it will involve significant extra costs to businesses and a significant increase in enforcement by the Council.
- 7.3 There was recently debate at the Scottish Food Enforcement Liaison Committee, the national co-ordinating body on food control and enforcement, on these issues and we are awaiting the results of further deliberations on how this guidance can be enforced fairly, practically and consistently before we set out our strategy to enforce the guidance in Inverclyde. It is our intention when this is

clear to bring an update report to committee together with a revised Enforcement Policy setting out how we aim to implement the guidance. Should the guidance remain in its current state however there may be implications for the staffing requirements of the team.

8.0 FSA Review of Food Safety Official Controls Delivery

- 8.1 A paper was presented at the FSA board meeting on 25 January 2011 (Appendix 3) summarising the difficulties the FSA perceives with the current food controls delivery in the UK. These centre on the FSA's role as the UK's central competent authority to the EU, which makes the agency responsible to the EU for any shortcomings in the delivery of controls whilst not carrying out the vast majority of such controls itself.
- 8.2 The FSA board agreed that there should be a review of the current delivery mechanisms recommending any changes required to its July meeting. Changes recommended might involve removing food safety controls from local authorities to either a national UK delivery body under the FSA or to a Scottish body under the FSAS. Obviously such changes would require primary legislation and it would seem unlikely to find favour currently given the recent reductions in quangos. It could also be argued that the FSA has default powers to take over enforcement from local authorities where these are found to be failing by the audit process but it has never chosen to exercise these powers in spite of a number of examples of very poor performance in audits in England.
- 8.3 Should such a course of action be pursued there would be serious implications for the maintenance of Environmental Health services as a whole in local authorities as food control is a major plank of their responsibilities. There would be a knock on effect on the ability to retain and train a competent workforce in a number of related areas such as public health. The outcome of the FSA review and any implications of its recommendations will be reported to committee in due course.

9.0 IMPLICATIONS

9.1 Finance

There are no financial implications arising from this report. Any such arising from the issues raised will be dealt with in future reports.

9.2 Personnel

There are no personnel implications arising from this report. Any such arising from the issues raised will be dealt with in future reports.

9.3 Legal

There are no legal implications arising from this report. Any such arising from the issues raised will be dealt with in future reports.

9.4 Equalities

none

10.0 Background Papers

- 10.1
1. Official Food and Feed Controls Service Plan – Inverclyde 2011/12
 2. E. Coli O157: Control of cross-contamination Guidance for food business operators and enforcement authorities (FSA 2011)
 3. Food Safety Official Controls Delivery (FSA Board Paper 25 January 2011)

Inverclyde Council Official Feed and Food Controls Service

1. Service Aims and Objectives

<p>1.1 Aims and Objectives</p>	<p>The aims of the Inverclyde Council's Safer & Inclusive Communities Service in relation to Food and Feed Control are</p> <ul style="list-style-type: none">• To continue to carry out a risk based inspection and sampling programme covering all food businesses for both food safety and food standards within Inverclyde in line with documented procedures, based on the relevant legislation, the Food Law Code of Practice and guidance notes.• To work with local businesses in as open and transparent a manner as possible in order to help them where necessary, improve the safety of food and level of compliance with relevant legislation.• To respond efficiently to complaints about food quality, food premises, food labelling or food composition, originating from premises or purchases made within Inverclyde.• To play a full role in the West of Scotland Food Liaison Group and to co-operate in full with the Scottish Food Enforcement Liaison Committee, the Food Standards Agency Scotland and The Royal Environmental Health Institute of Scotland to improve consistency and best practice in the role of food enforcement among Scottish local authorities.• To continue to provide advice and guidance on all food safety matters to the businesses of Inverclyde.• To ensure the safety and compliance of feeding stuffs in Inverclyde in line with the Code of Practice to reduce the risk arising to animal and human health.
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<p>1.2 Links to corporate objectives and plans</p>	<p>In carrying out the above effectively the service will contribute to the following corporate outcomes (Inverclyde Corporate Plan 2007-11):</p> <ul style="list-style-type: none"> • Educated, Informed, Responsible Citizens • Healthy, Caring Communities • A Thriving, Diverse Local Economy • A Modern, Innovative Organisation <p>We will also contribute to the following outcomes from Inverclyde Council's Single Outcome Agreement:</p> <ul style="list-style-type: none"> • SOA 4 – Economic activity in Inverclyde is increased, and skills development enables both those in work and those furthest from the labour market to realise their full potential • SOA5 – The health of local people is improved, combating health inequality and promoting healthy lifestyles
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2. Background

<p>2.1 Profile of the Local Authority</p>	<p>Inverclyde covers an area of 61 square miles stretching along the south bank of the estuary of the River Clyde. Inverclyde is one of the smaller local authorities in Scotland with a population of 81,540. The main towns of Greenock, Port Glasgow and Gourock sit on the Firth of Clyde. The towns provide a marked contrast to the coastal settlements of Inverkip and Wemyss Bay, which lie to the south west of the area, and the villages of Kilmacolm and Quarrier's Village which are located further inland.</p> <p>Demographic trends have shown a marked decrease in population in recent years with the majority of those leaving being young. Overall this is likely to result in a far higher proportion of over 60s in the population in the future. Inverclyde also has substantial areas of deprivation.</p> <p>In the 2009 Scottish Index of Multiple Deprivation 17 (15.5%) of Inverclyde's 110 datazones were in the 5% most deprived datazones in Scotland. This is the second highest local share of any authority in Scotland with obvious effects on the general health and life expectancy in the area.</p>
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<p>2.2 Organisational Structure</p>	<p>A full Council Structure is attached as Appendix 1. Specifically however the food & feed service is part of the Food & Health Team with responsibilities as follows:</p> <div style="text-align: center;"> <pre> graph TD A[Corporate Director Education & Communities – Albert Henderson] --> B[Head of Safer & Inclusive Communities – John Arthur (Head of Food Service)] B --> C[Health Protection Manager – Martin McNab (Lead Officer Food Safety & Standards)] C --> D[Food & Health Team leader – Michael Lapsley] D --> E[Roisin Dillon Senior TSO (Lead Officer Feed)] </pre> </div> <p>As can be seen from the above Safer & Inclusive Communities is part of the Education & Communities Directorate. For the purposes of Food & Feed however the service reports to the Safe, Sustainable Communities Committee.</p>
<p>2.3 Scope of the Feed and Food Service</p>	<p>The Food and Health Team within Safer Communities is responsible for delivering all aspects of Food Safety and Standards enforcement within Inverclyde. The team also has responsibility for Trading Standards (including Animal Feed), Port Health, Infectious Disease Control, Animal Health and Private Water Supplies.</p> <p>The Food & Health Team consists of a Team Leader, two Environmental Health Officers (both also working with the Environment & Safety Team), a Food Safety Officer, a Senior Trading Standards Officer and a Trading Standards Officer.</p> <p>With the exception of the Trading Standards staff all are involved in Food Safety and Standards enforcement. The TSOs are involved in feed enforcement. Two further EHOs from other teams in the</p>

	<p>service contribute to food enforcement.</p>
<p>2.4 Demands on the Feed and Food Service</p>	<p>Within Inverclyde at 1st April 2011 there were 666 food premises of various types and sizes over which it has enforcement responsibility.</p> <p>This includes 2 premises approved under product specific legislation giving each of these businesses a unique Approval Number. Both are involved in meat products production with one producing meat preparations.</p> <p>Of the 666 premises by classification on 1 April 2011 there are 3 primary producers, 16 manufacturers/packers, 5 distributors, 165 retailers, 148 restaurants & caterers, 94 caring establishments, 16 hotels/guest-houses, 31 mobile food units, 83 pubs/clubs, 69 take-aways and 36 schools/colleges.</p> <p>Work is currently ongoing to categorise feed premises on the new back office system.</p> <p>The food service is delivered from 40 West Stewart Street in Greenock and operates during normal working hours Monday to Friday. In the event of a food related emergency senior members of Safer Communities' staff are contactable out of hours. Contact numbers are available to both the FSAS and Greater Glasgow & Clyde Health Board.</p> <p>There are no significant additional external factors impacting on the service. The percentage of business owners whose first language is not English is no greater than average. The number of manufacturers is small and, although Greenock has a busy port, at present no food or feed is imported. There have however been recent approaches from an importer considering using Greenock Ocean Terminal to import food which would have implications for the workload and staffing level of the team.</p> <p>Possibly the most significant factor which could affect the authority's ability to deliver its food and feed control programme is the relatively small size of the service. This means that a large outbreak or event could have a disproportionate effect on the service. Work is currently ongoing with other authorities in the Health Board area to explore how mutual aid could be deployed in such an event.</p>

2.5 Regulation Policy	The Food Service currently operates in line with a Food Safety Enforcement Policy to ensure that compliance with food law is achieved in a proportionate, transparent and consistent manner. The Enforcement Policy is currently undergoing revision. The potential implications of the Food Standard Agency's recent guidance on cross contamination ¹ could have a significant impact on the final document.
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3. Service Delivery

3.1 Interventions at Food and Feeding stuffs establishments	<p>Programmed Food Hygiene interventions for 2011-12:</p> <p>There are 392 programmed inspections/interventions due in 2011/12. These are made up of programmed inspections in premises categories A-D made up of 20 Category A (10 premises), 84 Category B, 216 Category C and 25 Category D. There are additionally 47 Category E Premises due intervention.</p> <p>The cross contamination guidance referred to in 2.5 above has the potential to significantly increase the frequency of inspection for higher risk premises and to lead to an increase in the incidence of enforcement actions. The implications of this guidance will be addressed in a rewrite of the Service's Enforcement Policy once a general consensus has been reached nationally on how this guidance can be implemented fairly and consistently across Scotland.</p> <p>Programmed Food Standards interventions for 2011/12:</p> <p>There are 109 Food Standards interventions programmed for 2011/12 made up of 63 Category B and 46 Category C.</p> <p>Programmed Feed interventions for 2011/12:</p> <p>Feed interventions will in the main be carried out in concert with primary production visits and animal health visits to reduce the burden on local farms and businesses. Five programmed primary production</p>
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¹ [E COLI 0157 CONTROL OF CROSS CONTAMINATION Guidance for food business operators and enforcement authorities](#)

	<p>visits will be carried out in 2011/12 in addition to any requested or reactive visits. Annual sampling projects also take place in the West of Scotland.</p>
<p>3.2 Feed and Food Complaints</p>	<p>The food service deals with a varying number and type of food complaints from both members of the public about locally purchased food and from other enforcement authorities regarding locally produced food.</p> <p>All complaints are handled in line with our documented policy and are thoroughly investigated. The majority of complaints do not result in formal action; however they maybe referred to the procurator fiscal in accordance with the Enforcement Policy.</p> <p>Last year the service dealt with 56 food complaints of which 34 related to the hygiene of premises.</p>
<p>3.3 Home Authority Principle and Primary Authority Scheme</p>	<p>At present Inverclyde Council has formal Home Authority agreements with two businesses based in the area. Informal arrangements however exist with a number of other businesses and we would always seek to respond to all enforcing authority questions on food produced and labelled within Inverclyde. At present Inverclyde does not have any Primary Authority partnerships.</p>
<p>3.4 Advice to Business</p>	<p>The food service is proactive in advising businesses in the course of normal contacts. It is also happy to visit sites of proposed businesses on request to advise on layout and structural finishes. The service operates an open door policy and is happy to advise on any food related matters including labelling.</p> <p>The Service launched the Food Hygiene Information Scheme in Inverclyde in October 2010 which led to an increase in advisory visits in 2010/11; it is likely that FSA's Cross Contamination guidance will lead to a significant increase in advisory visits in 2011/12.</p>
<p>3.5 Feed and Food Sampling</p>	<p>Inverclyde participates in sampling programmes instituted by a number of bodies, such as the West of Scotland Food Liaison Group.</p> <p>All of the analysis is carried out by Glasgow Scientific Services which is a NAMAS accredited laboratory.</p>

	<p>Inverclyde has a documented policy for sampling. An annual sampling programme is produced as part of the policy.</p> <p>The chemical samples included food samples, food complaints and radiation samples. Sampling is carried out to monitor food poisoning incidents, complaints, manufacturing processes and general hygiene trends. It is strongly based on locally produced foods.</p> <p>Although Inverclyde has a major port in the Greenock Ocean Terminal, at the time of writing there is no food imported to the UK through the port. Were this to change a significant amount of our sampling effort would be redirected to address this. Contact with a possible importer suggests that there is a possibility of this occurring in 2011/12.</p> <p>In 2010/11 approx 226 food samples were taken.</p> <p>We hope to be able to participate in the Scottish Food Surveillance System at some stage in the future. Indications at present suggest that there would be a cost to the Council in doing so however, contrary to previous assurances, and the potential workload arising from the cross contamination guidance is likely to preclude participation in the short term.</p> <p>Annual sampling for feed is carried out in accordance with a planned programme devised jointly by the authorities in the West of Scotland.</p>
<p>3.6 Control and Investigation of Outbreaks and Food Related Infectious Disease</p>	<p>The Food Section liaises with Greater Glasgow & Clyde Health Board through the Consultant in Public Health Medicine in the investigation of food poisoning incidents within Inverclyde. A protocol is in place dealing with the investigation of isolates. In case of a major outbreak an outbreak control plan is in place.</p> <p>A major outbreak of food poisoning would inevitably have a long term impact on the day to day work of the section given the relatively low staff numbers. The Greater Glasgow & Clyde Joint Health Protection Plan has made the development of mutual aid agreements between authorities a priority and work is currently ongoing with this.</p>

<p>3.7 Feed/Food Safety Incidents</p>	<p>Inverclyde is part of an electronic alert system operated by Food Standards Agency Scotland. Contact can be made with the Head of Service or Service Managers on a 24 hour basis. The Food Section is committed to fully implement the Code of Practice with regard to food safety incidents. Incoming Food Alerts are automatically cascaded to all members of the team.</p>
<p>3.8 Liaison with Other Organisations</p>	<p>To ensure that enforcement action taken by Inverclyde's Food Section is consistent with those of neighbouring authorities, the Food Section is involved with the following organisations; the West of Scotland Food Liaison Group which represents 14 of Scotland's 32 authorities and includes representatives from Glasgow Scientific Services, through the liaison group with the Scottish Food Enforcement Liaison Committee (SFELC) and the Food Standards Agency.</p> <p>The Trading Standards section liaises with other authorities through participation in SCOTSS (Society of Chief Officers of Trading Standards in Scotland) and its appropriate sub-groups.</p> <p>There is close Liaison with Greater Glasgow & Clyde Health Board and the other authorities in its area at the Public Health (Health Protection) Liaison Working Group. This group include representatives from Animal Health, SEPA, Scottish water and Health Protection Scotland.</p>
<p>3.9 Feed and Food Safety and Standards promotional work, and other non-official controls interventions</p>	<p>The main emphasis of promotional work to be undertaken with businesses and the public in 2011/12 is likely to involve the promotion of FHIS locally in concert with a possible national campaign by FSAS. There is likely to also be a need to promote the FSA's Cross Contamination Guidance to businesses locally.</p>

4. Resources

4.1 Financial Allocation	<p>Staffing Costs for 2011/12 - £135,000 (including approx £7,000 for admin support)</p> <p>Travel & Subsistence - £1,200 (estimated)</p> <p>IT – There was substantial investment in a new back office system in 2008/09 (approx £80,000 of which the food safety element would have been approx £25,000) subsequently Food & Feed enforcement’s share of annual licence fees is estimated at £2,000 per annum.</p> <p>Sampling – Overall the Service spent approx £100,000 on sampling in 2010/11 of which approximately 50% or £50,000 was spent on food & feed sampling. Costs for 2011/12 are expected to be similar.</p> <p>Other costs including property costs, printing etc. estimated at £10,000.</p> <p>No growth is expected in 2011/12 beyond any incremental increase in salary costs so the estimated cost of the service in 2011/12 is approximately £196,000.</p> <p>n.b. the above figures are provisional as of 1 April however final outturn is expected to be very close to the estimates</p>
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4.2 Staffing Allocation	<p>At the time of writing there are a total of 2.9 qualified FTEs working in the Food & Feed. These are made up of a proportion of the working time of 8 staff in total. Of those 8, 4 are authorised at the highest level (to serve EPN/HEPN, RAN etc) and 3 at a medium level (service of IN/HIN etc). One is fully authorised as the lead officer for feed.</p> <p>A further 0.25 FTEs contribute to the service as support staff.</p>
4.3 Staff Development Plan	<p>All staff members attend external events for CPD as far as availability allows. Being a relatively small service, staff CPD in food & feed enforcement can largely be gained through a combination of FSA low cost training events and internal staff development e.g. consistency exercises. Full records are kept of staff training and these are reviewed regularly to ensure that staff with a need to attend particular courses (e.g. FSA HACCP auditing etc.) are identified and given preference when places become available.</p>

5. Quality Assessment

5.1 Quality assessment and internal monitoring	<p>The Food Section currently has a system for monitoring the quality of food hygiene inspection. These are reviewed on a regular basis to take account of any changes in external factors, e.g. Code of Practice requirements, or internal factors, for example the forthcoming launch of FHIS.</p> <p>As a small authority, the use of a formal quality system is considered to require a disproportionate amount of officer time and expense to achieve any benefit.</p>
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6. Review

6.1 Review against the Service Plan	<p>It is our intention to review service delivery and report on performance to committee on the 2011/12 Service Plan either via the directorate plan or via a separate report.</p>
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6.2 Identification of any Variation from the Service Plan	The Team Leader Food and Health will identify any variance from the plan and identify the reasons e.g. large food poisoning outbreak or national food crisis. It is expected that the enforcement of the FSA cross contamination guidance may lead to significant additional workload and hence variance from the plan.
6.3 Areas of Improvement	Where a review of the service plan highlights an area for improvement this will be incorporated in the plan for the following year.



E. COLI O157
CONTROL OF
CROSS-CONTAMINATION

Guidance for
food business operators
and enforcement authorities

If you require this information in an alternative format – such as audio, large print, Braille – please contact us.

CONTACT TELEPHONE 020 7276 8449

SUMMARY

Intended audience:	<p>This guidance is for food businesses of all sizes where both raw food and ready-to-eat foods are handled.</p> <p><i>Raw food</i> in this context means raw meat and any raw ingredients that are potential sources of <i>E. coli</i> O157.</p> <p><i>Ready-to-eat foods</i> are foods that will not be cooked or reheated before being eaten and include foods such as cooked meats, sandwiches, cheese, salads and desserts.</p>
Regional coverage:	<p>This guidance applies across the UK.</p>
Purpose:	<p>The purpose of this document is to provide guidance on the steps that food businesses need to take in order to control cross-contamination between raw foods and ready-to-eat foods where <i>E. coli</i> O157 is a hazard. Businesses are required to produce safe food and this guidance is intended to assist businesses with meeting that duty.</p>
Legal status:	<p>This document provides guidance on compliance with applicable food hygiene legislation contained in Regulation (EC) No 852/2004 but also contains best practice recommendations.</p>
	<p>Best practice recommendations are highlighted in grey boxes.</p>
Essential actions to comply with regulation(s):	<p>Food business operators must put in place food safety management procedures based on the principles of HACCP (Hazard Analysis Critical Control Point). Where applicable, these must include effective controls to ensure that all ready-to-eat foods are protected against direct or indirect contamination from <i>E. coli</i> O157 arising from raw foods.</p> <p>This contamination can be controlled by:</p> <ul style="list-style-type: none"> • Separation, between equipment, materials and staff involved in handling raw food from those involved in handling ready-to-eat food. • Where separation is not physically possible, there

	<p>are limited circumstances where risks may be reduced through strict and consistent application of cleaning, disinfection and handwashing procedures, which ensure the removal of <i>E. coli</i> O157 from surfaces, equipment and hands on every occasion before coming into contact with ready-to-eat foods.</p> <p>These procedures need to ensure that:</p> <ul style="list-style-type: none">• Adequate facilities are provided for handwashing and that staff are trained in handwashing techniques• Appropriate products are selected for cleaning and disinfection of surfaces and are used in accordance with manufacturer's instructions.
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REVIEW OF GUIDANCE

The Agency has, as far as possible, considered the suggestions offered in response to the public consultation in formulating this guidance. The guidance is intended as a source document for both industry and enforcers from which messages can be taken to produce further targeted guidance for specific audiences. This recognises the emerging findings from our work on understanding behaviours which emphasised the need for effective, targeted messages. The Agency will be taking forward a further programme of work to consider how best to target specific audiences and to inform this work. We are seeking feedback from FBOs and enforcers on implementation of this guidance.

Please send your feedback on this guidance either by email to:

controllingecoli@foodstandards.gsi.gov.uk

Or in hardcopy to:

**Enforcement and Local Authority Delivery Division, Quality Assurance
Delivery Branch
Aviation House, 125 Kingsway
London
WC2B 6NH**

REVISION HISTORY

This guidance follows the Government [Code of Practice on Guidance](#). If you believe this guidance breaches the Code for any reason, please contact us using the number on the front sheet. If you have any comments on the guidance, again please contact us on the number on the front sheet. This document is scheduled for review by the end of December 2011.

Revision No.	Revision date	Purpose of revision	Revised by
0	15/02/2011	First Issue	

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EXECUTIVE SUMMARY

Background

This guidance sets out the strict precautions needed in food businesses to ensure that consumers are protected from the risk of an isolated instance of low-level contamination of ready-to-eat food with *E. coli* O157. It applies to all sectors except primary production (e.g. farming) and is therefore applicable to retail, catering, and other processing sectors.

E. coli O157 is a particularly dangerous type of bacteria because it can cause serious, untreatable, illness and even death from very low-levels of contamination of ready-to-eat food. Because *E. coli* O157 survives at freezer, chill and ambient temperatures, measures to control cross-contamination apply to all of these environments. Although *E. coli* O157 is the key focus of this guidance, the measures outlined will also help in the control of other food poisoning bacteria, such as campylobacter and salmonella.

The risk of *E. coli* O157 cross-contamination should be considered wherever raw foods such as raw meat and unwashed vegetables are handled and where ready-to-eat foods are also handled. Without strict controls, *E. coli* O157 can be spread throughout any food processing environment. It is therefore essential that ready-to-eat foods are at all times handled and stored in clean areas where controls ensure the environment is free from *E. coli* O157 contamination.

Physical separation

Controls must ensure that surfaces, equipment, hands, clothing etc that are designated as clean will never become contaminated by *E. coli* O157, because no further controls will prevent that contamination spreading within the clean area. Food premises should be designed to enable adequate separation.

The only reliable way to prevent cross contamination of ready-to-eat foods with *E. coli* O157 is through strict physical separation of clean environments, where ready-to-eat foods are handled and stored, from any other surfaces or equipment that are not designated for use in the clean area. This will require the use of separate equipment and utensils. Complex equipment such as vacuum packers, slicers and mincing machines should never be used for both raw foods and ready-to-

eat foods and separate machines should be provided. These must also be hygienically designed.

Adequate separation requires thorough consideration of everything used in a clean area, including packaging, cleaning materials, cash registers, aprons, gloves, pens etc. If these are overlooked then contamination can enter the clean area and spread without any way of detecting it or controlling the surfaces affected.

Handwashing

The movement of staff from handling raw food to handling ready-to-eat foods should be minimised as far as possible, but where it is unavoidable, handwashing controls must ensure that a proper technique is followed on all occasions. Once hands have been washed, procedures must ensure that they are not re-contaminated by contact with taps. Hygienic hand rubs, such as alcohol gels, can be considered as an additional precaution but should not be used as an alternative to effective handwashing.

Disinfection

Disinfection by heat using appropriate time/temperature combinations can be effective at destroying *E. coli* O157. The temperatures required are generally achieved in commercial dishwashers and in standard hot wash laundry cycles.

Disinfection using chemical disinfectants or sanitisers should not be substituted for physical separation as a critical control for *E. coli* O157 cross-contamination. However, in the limited cases set out in the guidance (sinks for cleaning and disinfecting food equipment and non-food-contact surfaces such as worktops and walls), it may be the only practicable control measure. In such cases, the use of disinfectants or sanitisers that meet BS EN 1276:1997 or BS EN 13697:2001 can be considered appropriate. This is provided that they are applied to visibly clean surfaces, and are used strictly in accordance with the manufacturer's instructions relating to proper dilution of the chemical, the effective temperature range and the necessary contact time. Since effective chemical disinfection can only be achieved on visibly clean surfaces, a cleaning stage is required first.

Effective chemical disinfection is an essential prerequisite hygiene measure throughout the food industry and the guidance in this document can be used more generally for the selection and use of disinfectants.

Documented procedures

Robust documented procedures are essential for ensuring that measures for controlling *E. coli* O157 cross-contamination are being adhered to. Measures that are critical for control of *E. coli* O157 must be valid and this document provides advice that can be used to draw up valid procedures. These procedures will need to be supported by training of all relevant staff. Training will need to ensure that staff fully understand and implement arrangements for separation and the maintenance of clean areas. Training will also need to ensure that staff are able to carry out proper handwashing technique and fully understand when handwashing is critical to protect ready-to-eat foods and the integrity of designated clean areas. Similarly, training in the correct use of disinfectants and sanitisers is critical to their effectiveness.

Control measures

Supervision must ensure that critical cross-contamination controls are implemented at all times. If a breakdown in procedure is detected, it must be considered a serious incident and the food business operator must take immediate steps to ensure that no food placed at risk from *E. coli* O157 cross-contamination is supplied for consumption. Effective action must also be taken in respect of any product that has already been placed on the market.

Enforcement

The role of enforcing authorities is to protect consumers where a food business operator has not implemented adequate controls or appropriate corrective actions. Where an enforcing authority identifies that critical cross-contamination controls are inadequate or corrective actions have not been properly implemented, it must intervene and take all appropriate action to protect public health. Enforcing authorities must always consider the use of Hygiene Emergency Prohibition Notices where inadequate control presents a risk of cross-contamination of ready-to-eat foods by *E. coli* O157. Enforcing authorities should take possession of food intended for use as a ready-to-eat product for the purposes of destruction if it has not been produced, processed or distributed in accordance with statutory hygiene requirements and it has been exposed to the risk of *E. coli* O157 cross-contamination.

INTRODUCTION

1. This guidance has been developed by the Food Standards Agency in response to the serious foodborne *E. coli* O157 outbreaks that were reported in Scotland during 1996 and Wales during 2005. Both of these outbreaks resulted in the deaths of some affected individuals and in serious long-term health problems for others. Both the Scotland and Wales outbreaks were attributed to cross-contamination arising from poorly managed food handling practices.

Intended audience

2. This document provides guidance to food business operators (FBOs) and enforcement authorities on the measures required to control cross-contamination involving *E. coli* O157. It applies to all food businesses that handle raw and ready-to-eat foods, where control measures are necessary to manage the risk of cross-contamination with *E. coli* O157. This guidance does not apply to primary producers (i.e. farmers and growers).

Purpose of guidance

3. This guidance aims to increase recognition of the threat that *E. coli* O157 poses to public health and the need for stringent measures required during food production to control the particular cross-contamination risks associated with this pathogen. It should be noted that although *E. coli* O157 is the key focus of this guidance, the measures outlined will also help in the control of cross-contamination risks posed by other pathogens such as campylobacter and salmonella.
4. The controls set out in this guidance will be **necessary** in all circumstances where raw foodstuffs, which have the potential to be contaminated with *E. coli* O157, are handled in the same establishment as ready-to-eat food. Examples of raw foodstuffs known to be potential sources of *E. coli* O157 are described in paragraph 17 and include the following:
 - Raw meat

- Raw root vegetables, fruit or other vegetables likely to have been contaminated by soil, excluding products that are specifically sold as ready-to-eat.
5. *E. coli* O157 outbreaks have also been attributed to the consumption of raw milk and raw milk products, as well as water from untreated supplies. Food businesses using private water supplies will be aware of specialist requirements for ensuring the safety of the supply. Dairy establishments handling raw milk should have well-established systems to control cross-contamination.
 6. FBOs should apply the measures set out in this guidance in all circumstances where they have reasonable grounds to believe that *E. coli* O157 may be present in food ingredients or in any other material entering a food establishment where ready-to-eat foods are also handled.
 7. Materials that are used for the wrapping and packaging of foods, which may be contaminated with *E. coli* O157, are also treated as a potential route for cross-contamination. Guidance is also provided on measures for avoiding the contamination of the outer surfaces of pre-packed foods in order to minimise the potential risk to catering businesses and consumers. Potential indirect routes for cross-contamination via food handlers are also covered.
 8. This guidance includes technical control measures in relation to cleaning and decontamination protocols for equipment and surfaces required to reduce the cross-contamination risks associated with *E. coli* O157 and other foodborne pathogens.
 9. The decontamination of foods that may already contain *E. coli* O157 or other microbiological pathogens is not covered in this document. Such controls through cooking or other processing steps are covered in existing guidance published by the Food Standards Agency.

Legal status of guidance

10. This guidance has been produced to provide advice on how to comply with the legal requirements of Regulation (EC) No 852/2004 where they are applicable to controlling cross-contamination, and what is best practice in this area.

11. The guidance notes on legal requirements cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances. Further information about legal requirements relevant to controlling cross-contamination is provided in Annexe 1. Following the guidance notes will help you to comply with the law. Boxes throughout the text highlight key messages, these have been outlined in green. Compliance with the advice on best practice is **not** required by law. **To distinguish between the two types of information, all advice on best practice is in grey shaded boxes, with a heading of Best Practice.**
12. Businesses with specific queries may wish to seek the advice of their local enforcement agency that will usually be the environmental health department of the local authority.

GLOSSARY

Asymptomatic	Infection without symptoms.
Bactericidal	Capable of destroying bacteria.
Dual-use	The use of any equipment, at different times, for raw foods and ready-to-eat foods.
CE Mark	A manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation.
Clean area	An area within a food establishment that is specifically managed to ensure that harmful bacteria, including <i>E. coli</i> O157, have been effectively excluded from all surfaces (including hands) that will come into contact with ready-to-eat foods.
Cleaning	The physical removal of food debris, visible dirt, food particles and debris from surfaces, equipment, and fittings using hot water and a detergent.
Clean as you go	The frequent clean up of food waste and debris to avoid accumulation of food residues on equipment and surfaces.
Contact time	The period of time for which a disinfectant should be in contact with a surface to achieve the required level of disinfection.
Cross-contamination	The transfer of harmful bacteria from a contaminated food source to an uncontaminated food item either by direct or indirect contact.
Detergent	A cleansing substance (which does not have disinfectant properties) made from chemical compounds and used for general cleaning.
Disinfectant	A substance that is capable of destroying harmful bacteria when applied at a specified concentration and contact time.
Disinfection	The application, following general cleaning, of a bactericidal disinfecting agent or treatment to facilitate the removal of harmful bacteria from surfaces or equipment.
FBO	Food business operator.
Food safety requirements	The statutory requirements for safe food are defined in European Community food law. Regulation (EC) No 178/2002 requires that food must not be placed on the market if it does not meet the food safety requirements that are defined within in the regulation.
HACCP	Hazard Analysis and Critical Control Point. An internationally recognised food safety management system that identifies, evaluates, and controls hazards that are significant for food safety. European food law requires every FBO (except primary producers) to implement a food safety management system based on HACCP principles.

Infective dose	The number of pathogenic organisms that will cause infection in susceptible subjects.
Monitoring¹	The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control.
Potable water	Water that is fit for human consumption and free from colour, taint, odour or pathogens.
Raw food	Raw meat and any raw foods that are potential sources of <i>E. coli</i> O157.
Raw meat	Uncooked meat (including mince and sausages), poultry, game and offal.
Ready-to-eat food	Foodstuffs or ingredients that can safely be consumed without further heating or other processing, such as cooked meat, fruit, salads, pies, cheeses and sandwiches.
Sanitiser	A substance that combines disinfectant and detergent in a single product.
Validation¹	Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.
Verification¹	The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended.
Visibly clean	Free from any visible grease or film and solid matter.

¹ Taken from Guidelines for the Validation of food safety control measures CAC/GL-2008
http://www.codexalimentarius.net/web/more_info.jsp?id_sta=11022

E. COLI O157 – WHY IS THERE A RISK?

13. Verotoxigenic *E. coli* (VTEC) is a group of toxin-producing strains of *Escherichia coli* that occur naturally in the gastrointestinal tract of ruminant animals, including cattle and sheep, which are pathogenic to humans. *E. coli* O157 is the VTEC strain that has been most commonly implicated in human infection in the UK.
14. *E. coli* O157 is a particularly dangerous organism because:
 - it is reported to have a very low infective dose (less than 100 bacteria) and can lead to serious illness and death
 - it has the ability to survive during refrigeration and freezing and in environments which have a low pH or reduced water activity
15. *E. coli* O157 infection can be asymptomatic or can result in symptoms ranging from abdominal pain, mild diarrhoea and bloody diarrhoea (haemorrhagic colitis) to serious conditions including haemolytic uraemic syndrome (HUS). HUS can lead to renal failure, which may be fatal or be associated with long-term complications such as kidney disease, hypertension and neurological disorders. Young children, the elderly and immunocompromised individuals are particularly at risk, and there is no specific treatment for the illness. In a small number of cases VTEC infection may also develop into thrombotic thrombocytopenic purpura (TTP) in adults. TTP is a rare blood condition that causes small clots to form within the circulation. This results in a low platelet count, renal failure and severe neurological complications.

The low infective dose, the severity of the illness, and the lack of effective treatment means that every consumer needs to be protected from the risk of an isolated instance of low-level contamination of food with *E. coli* O157

This will require food businesses to implement the highest standard of controls to prevent cross-contamination

SOURCES OF *E. COLI* O157 CONTAMINATION IN FOOD BUSINESSES

16. *E. coli* O157 is a faecal pathogen and people can become infected through exposure to animal faecal matter via environmental routes. Potential routes include direct contact with ruminant farm animals or livestock, soil and/or manure through farming or recreational activities and exposure to contaminated private water, recreational water or irrigation supplies. As ruminant animals are the key reservoirs for *E. coli* O157, the raw meat and raw milk from these animals are also potential sources of this organism.
17. Contaminated food is an important vehicle for *E. coli* O157 infection. The key sources of *E. coli* O157 within a food production environment are provided below. FBOs concerned with the handling or production of ready-to-eat foods should, at all times, take full account of these risk factors when developing their HACCP-based food safety management systems in order to protect consumers from *E. coli* O157.

a) **Meat**

E. coli O157 occurs naturally in the digestive tract of healthy animals and can also be found on the animal's hide, fleece, feathers and skin. The bacteria are shed from the animal in their faecal matter and can contaminate the surfaces of raw meat during slaughter, dressing and packaging. While the pathogen is most commonly associated with red meat from ruminant animals (cattle, sheep and goats), it has also been isolated from pork and chicken. The mincing of meat can spread surface contamination throughout the product and provides an opportunity for the growth of bacteria.

b) **Fresh produce**

Vegetables and fruits that have been supplied to food businesses as ready-to-eat, should already have been subjected to validated procedures to ensure bacterial load is reduced to levels that do not present a risk to health. The FSA recommends that bagged ready-to-eat fresh produce does not need to be rewashed. In environments where potential sources of *E. coli* O157 are being handled, the rewashing of products supplied as ready-to-eat could introduce an additional cross-contamination risk.

Leafy and root vegetables that have not been supplied as ready-to-eat will not have been subject to controlled washing procedures and should be classed as a potential hazard in terms of cross-contamination of *E. coli* O157, particularly if soil or manure is visible.

c) Raw milk

Raw, unpasteurised milk, as well as products made from unpasteurised milk have been implicated in *E. coli* O157 infection. Therefore, raw milk and raw milk products supplied to a food business should always be treated as a potential source of contamination unless supplied as ready-to-eat. Cheese manufactured from unpasteurised milk and supplied as a ready-to-eat product should be treated accordingly. The processing of raw milk in the manufacture of ready-to-eat foods is beyond the scope of this guidance.

d) Water supplies

Water is an important potential source of microbiological hazards because harmful bacteria may survive in water for months. Water supplied to food businesses, including private supplies, must meet potable water standards.

E. COLI O157 CROSS-CONTAMINATION RISKS IN FOOD BUSINESSES

18. *E. coli* O157 is not detectable in contaminated foods by the naked eye and does not cause noticeable food spoilage. When establishing controls to prevent cross-contamination between raw foods and ready-to-eat foods it is important to take into account that *E. coli* O157 is capable of surviving during refrigeration and freezing, and in foods that have a low pH or reduced water activity.
19. Contamination can be spread from one surface, food product or waste product to another, either by direct contact with raw food or indirect contact with contaminated hands, clothing, equipment, or inanimate objects. This spread can only be prevented by adhering to **strict** food safety management procedures in all areas involving the storing and handling of foods including surfaces, equipment, and the personal hygiene of staff.
20. The following scenarios illustrate some of the potential routes for cross-contamination:

a) Use of contaminated ingredients in foods that are ready-to-eat

FBOs that handle the types of foods listed in paragraph 17 must make themselves aware of the potential risks that they carry and ensure that HACCP-based food safety management procedures are designed to control cross-contamination risks from these foods. The list of key food sources provided in paragraph 17 is not exhaustive and FBOs should maintain an awareness of any new or emerging risks in relation to *E. coli* O157 in foods through trade bodies or other established sources of advice and guidance relevant to particular industry sectors.

b) Direct contact between raw foods and ready-to-eat foods

Incorrect storage or handling of potentially contaminated raw foods may result in transfer of *E. coli* O157 by direct contact with the raw food and ready-to-eat food items. Direct contact between foods can occur in a fridge, freezer or on a surface. There is a risk of *E. coli* O157 contamination if raw and ready-to-eat foods are not adequately separated, wrapped or stored in the correct place. For example, if raw meat is stored above ready-to-eat food in a fridge there is a risk of juice dripping from the raw meat onto food below.

c) Indirect contamination via food contact surfaces (including packaging materials) that come into contact with raw foods and subsequently come into contact with ready-to-eat foods.

E. coli O157 can remain on surfaces following direct contact with contaminated raw foods. Where temperature and environmental conditions are favourable, *E. coli* O157 is capable of surviving on a range of surfaces including wood, stainless steel and plastics. The presence of food debris or residues will provide a protective medium for *E. coli* O157 on surfaces, encouraging it to persist and grow.

Storage of packaging material is often overlooked and if located in areas subject to splashing of blood from raw meat it can present a vehicle for cross-contamination. This applies to all types of packaging such as cling-film, aluminium foil, plastic bags, greaseproof paper, cardboard boxes, vacuum pack bags etc. In addition, outer packaging such as crates, or cardboard boxes, used to transport raw foods may carry a risk of contamination and should be removed before foods are brought into a clean environment where ready-to-eat foods are to be handled.

d) Dual use of equipment and machinery for slicing, mincing or vacuum packing of raw and ready-to-eat foods

There is a major risk of cross-contamination where the same item of equipment, such as vacuum packers, slicing machines and mincers, are used to process raw food and ready-to-eat food. *E. coli* O157 may contaminate the surfaces of such equipment after use with raw foods. This contamination may not be adequately removed during the cleaning and disinfection process and this can result in any ready-to-eat foods, subsequently processed with the equipment, becoming contaminated.

e) Water spray/aerosols

Water spray resulting from the washing of contaminated food, equipment and hands or the use of running water from a contaminated supply could present a contamination risk for uncovered ready-to-eat foods.

f) Use of contaminated cleaning materials

Cleaning equipment, cloths and chemicals are all potential vehicles for the spread of *E. coli* O157. The frequency at which cleaning solutions are changed forms a critical part of cross-contamination control. It is also

important to ensure that equipment such as mops, brushes, sponges and buckets do not present a cross-contamination risk.

g) Poor personal hygiene practices

Objects that are touched by food handlers, such as money, pens, light switches, door handles, telephones and cash registers may act as vehicles for the spread of *E. coli* O157 through hand contact with contaminated surfaces.

h) Contamination through clothing, aprons and gloves

Cross-contamination can occur if food handlers handle both raw foods and ready-to-eat foods without adequate washing of hands and/or changing of clothes/aprons/gloves in between.

i) Contamination of foodstuffs by infected individuals

Food handlers infected by *E. coli* O157 will be a source of the bacteria and can contaminate the food or surfaces the food may come into contact with. No one suffering from or carrying an infection that could be transmitted through food should be allowed to handle food or enter the food-handling area if there is a risk of contaminating food. Staff handling food or working in a food handling area must report an infection or symptoms to management immediately². Further guidance is set out in the Agency's publication Food Handlers: Fitness to Work³.

***E. coli* O157 is not easily eliminated once contamination has occurred.**

It grows well at room temperatures, and is capable of surviving refrigeration and freezing. Effective controls are essential during all stages of food preparation and handling, including during frozen storage and cleaning procedures.

² Annex II, chapter VIII para 2 of Regulation (EC) No 852/2004

³ Food Handlers: Fitness to Work – A Practical Guide for Food Business Operators, <http://www.food.gov.uk/foodindustry/guidancenotes/hygguid/foodhandlersguide>

CONTROLLING THE RISK OF *E. COLI* O157 CROSS-CONTAMINATION

21. The designation of physically separate surfaces and equipment for raw and ready-to-eat foods is the only reliable means of adequately controlling *E. coli* O157 cross-contamination. In particular, the dual use of complex equipment, such as vacuum packing machines, for both raw and ready-to-eat foods **cannot** be implemented safely, even when cleaning and disinfection is applied in accordance with best practice.
22. In certain areas where complete separation is not physically possible, and alternative procedural controls are capable of reducing cross-contamination risks (see paragraphs 30-32), the highest standards of supervision and control are required to ensure that cleaning and disinfection procedures are carried out without fail and in all cases to appropriately high standards.
23. The law requires all food business operators to put in place food safety management procedures based on the principles of HACCP. In order to produce safe food, there must be effective procedures in place at every stage to manage cross-contamination hazards from *E. coli* O157 and other pathogens.
24. This section of the guidance covers in more detail issues to be considered to control the risk of cross-contamination.

Physical separation

25. The only reliable way to control cross-contamination with *E. coli* O157 between raw foods and ready-to-eat foods is by implementing physical separation.
26. In some food establishments, complete physical separation of raw and ready-to-eat food during handling and storage will be possible and achievable by the provision of separate working areas/rooms, storage facilities and staff that are physically separated at all times.
27. In food establishments where the above conditions are not achievable, the key to controlling cross-contamination will lie in maintaining designated clean areas for the handling and storage of ready-to-eat foods. A designated clean area is an area within a food establishment that is

specifically managed to ensure that harmful bacteria, including *E. coli* O157, have been effectively excluded from all surfaces (including hands) that will come into contact with ready-to-eat foods. All surfaces, hands, clothing etc in a designated clean area must remain free from any source of contamination so that food handlers can ensure there is no risk of *E. coli* O157 contamination being spread within the designated clean area. As soon as the critical control represented by a designated clean area is breached, there will be potential for contamination to spread from successive contacts between clean and contaminated surfaces. A clean area that has been compromised by possible *E. coli* O157 contamination presents an imminent risk. In these circumstances, operations must cease until all surfaces, equipment etc in the area have been decontaminated or replaced to ensure the risk of cross-contamination has been removed.

28. The following list describes situations when physical separation is **always** required:
- a) Separation in storage and display accommodation, including refrigerators and freezers, should always be sufficient to ensure that the designated clean areas for ready-to-eat foods are fully protected from the risk of *E. coli* O157 contamination. Where separate units are not provided, the clean storage areas should be clearly identifiable and sufficiently separated to ensure that the hands and clothing of staff are not exposed to contamination when loading or unloading ready-to-eat foods.
 - b) Under no circumstances should it be considered safe to use the same complex equipment, such as vacuum packing machines, slicers, mincers, etc, for both raw and ready-to-eat foods. Where, for example vacuum packing of ready-to-eat foods is carried out, the vacuum packing machine for this purpose should be located in a designated clean area where there is no risk from cross-contamination via splashes, hands, clothing, packaging or other equipment and should never be used for packing raw foods.

Dual use of complex equipment for raw and ready-to-eat foods should NEVER be regarded as a safe practice

- c) Separate chopping boards and utensils must be used for raw and ready-to-eat foods unless all such equipment is cleaned and disinfected by heat in a commercial dishwasher meeting the standard set out in paragraph 49, and there is a system in place to ensure that disinfected equipment is not subject to recontamination from raw foods.

- d) Wrapping and packaging materials for ready-to-eat foods should be stored in a designated clean area designed to protect it from cross-contamination and accessible by staff in a way that ensures their clothing and hands are not contaminated when loading or removing materials. Food business operators must ensure that the outside surfaces of any wrapping materials to be used for ready-to-eat food brought into a clean area are free from contamination. It may be possible to establish an assured standard of cleanliness through contractual arrangements with the supplier. In the absence of commercial guarantees, unpacking of ready-to-eat food should be undertaken in such a way that food is removed safely, without the risk of contaminating a clean area via food packaging.

Best practice:

Food business operators may consider decontaminating the outer surfaces of wrapping as an additional precaution for controlling cross-contamination risks

- e) Cash registers and similar non-food equipment should never present a cross-contamination risk and therefore should not be shared by staff handling ready-to-eat foods or working in clean areas and staff working in other areas. A single cash register can be used if appropriate measures are taken to prevent the spread of bacteria. If the cash register is kept in the clean area, care must be taken to ensure it is not contaminated by staff coming from areas outside the clean area. Similarly if the cash register is kept outside the clean area, staff from the clean area must ensure their hands and clothing are clean after using the cash register.
- f) Separate cleaning materials including cloths, sponges and mops should be provided, and materials for use in clean areas should be stored in designated clean areas accessible by staff in a way that ensures that their clothing and hands are not contaminated when storing or removing materials
29. Physical separation of the above should be achievable by all businesses involved in the handling of raw and ready-to-eat foods. A commercially desired throughput for an establishment should not constitute a physical limitation that prevents separation. In such cases operations should be scaled-down to a level in the establishment that permits physical separation.
30. It is recognised that in some establishments, there will be particular areas where it is not possible to achieve physical separation, but where it is possible to reduce the risk of cross-contamination through the

implementation of alternative procedural controls such as cleaning and disinfection. These areas should be limited to non-food contact surfaces, sinks and staff who handle raw and ready-to-eat foods at different times and FBOs should ensure that their alternative procedural controls are effective in controlling cross-contamination, and are implemented to a consistently high standard:

- a) Non-food contact surfaces such as worktops and walls, which may be subject to splashes from food, provided that all such surfaces are smooth, impervious and easily cleanable and are subject to strict application of cleaning and disinfection procedures, that are effective in removing *E. coli* O157, before there is any handling of ready-to-eat food in the area concerned.
 - b) The sharing of sinks for disinfection of equipment used for raw and ready-to-eat food, where the sinks and associated fittings and contact surfaces (e.g. taps) are themselves washed and disinfected between use. The flow of cleaning and disinfection should also ensure that utensils etc leaving the disinfection process enter a clean area fully protected against any source of recontamination. When the area is used to clean equipment intended for use in a clean area, staff hands and clothing should be clean at the start of the operation.
 - c) The use of the same staff for handling raw and ready-to-eat foods at different times. In such cases, any movement of staff from an area where raw food is handled into a clean area where ready-to-eat foods can be handled should be kept to an absolute minimum and will only be acceptable if procedures are put in place to monitor and manage strict adherence to documented handwashing procedures and appropriate use of clothing and aprons.
31. Food businesses should be aware that anything less than physical separation will involve a shift towards greater uncertainty regarding the stringency of risk reduction that can be achieved. Therefore, any use of alternative procedural controls in the circumstances listed in a. to c. above must be individually assessed. In particular, it is vital that full consideration is given to the monitoring and management arrangements required to ensure proper implementation of these procedures.
32. The use of alternative procedural controls should not continue if they are not fully and rigorously implemented at all times. If procedural failure is

detected, the safety of handling both raw and ready-to-eat foods at the establishment should be reassessed.

Cleaning, disinfection, personal hygiene and handling practices

33. FBOs must ensure that cleaning and disinfection procedures are in place that will ensure effective removal of *E. coli* O157 and other pathogens from all surfaces and equipment involved in food preparation. FBOs must also ensure that personal hygiene and handwashing procedures are implemented to the highest standards to prevent cross-contamination, that staff are trained on these and that all procedures are regularly monitored to ensure they are consistently maintained. It is **critical** that all procedures are strictly adhered to on **every** occasion prior to contact with ready-to-eat foods. Management of these procedures is particularly important in situations where it is not possible to achieve complete physical separation. These issues are considered in more detail in the paragraphs below.

Cleaning and disinfection

34. Understanding the processes required to effectively decontaminate surfaces is essential in minimising the cross-contamination risks associated with *E. coli* O157 and other pathogens. This can be carried out using **chemical** or **non-chemical** disinfection methods.

Chemical disinfection

35. There are a number of different types of cleaning products on the market and confusion between these types of product and about how they must be used can lead to poor disinfection procedures that allow harmful bacteria to remain on surfaces and equipment. It is important that staff understand what these chemicals do and that the correct products, purchased from reputable suppliers, are always used in accordance with the manufacturer's instructions.
36. As a general guide:
 - **Detergents** are products used for general cleaning. These do not have disinfectant properties and, if used on their own, are **not** capable of destroying harmful bacteria such as *E. coli* O157.

- **Disinfectants** are products that are capable of destroying harmful bacteria when applied to visibly clean surfaces at a specified dilution and contact time.
 - **Sanitisers** are products that combine a disinfectant and a detergent in a single product. This means that the same product can be used to provide a visibly clean surface and it must be used a second time in order to disinfect the surface.
37. Effective of cleaning must use a combination of physical cleaning, using a detergent, followed by a disinfectant used at the correct temperature, contact time and dilution.
38. Chemical disinfection should be carried out using a **two-stage** process:

Stage 1: General cleaning using a detergent

General cleaning involves the physical removal of visible dirt, food particles and debris from surfaces and equipment that come into contact with food along with the removal of waste from areas where food processing occurs. The detergents selected for use in each situation must be capable of removing all food debris, solids and grease. General cleaning should always be completed by rinsing to ensure thorough removal of all residues from the surface prior to stage 2.

Stage 2: Disinfection

Disinfectants that have been proven capable of destroying disease-causing bacteria should be applied after general cleaning to reduce microbial contamination to an acceptable level. Disinfection can only be successfully carried out on surfaces that have been thoroughly cleaned to remove grease and other dirt, as the effectiveness of disinfection is reduced in the presence of food matter.

39. Different types of disinfectants require different dilutions and contact times. These are specified and validated by the manufacturer and the FBO must follow the manufacturer's instructions for dilution and contact time to ensure the product is effective. Disinfection should be followed by a final rinse of the surface or equipment with potable water to remove any remaining chemical, unless it is formulated for use without a final rinse.

Disinfection will only be effective when carried out on a visibly clean surface that is free from grease, film or solid matter.

For a disinfectant to be effective in destroying bacteria, the correct dilution and contact time must be followed according to the manufacturer's instructions.

Standards for disinfectants

40. There are two officially recognised laboratory standards for assessing the effectiveness of disinfectants against a range of microorganisms, these are:
 - BS EN 1276:1997
 - BS EN 13697:2001
41. These standards demonstrate that a disinfectant is capable of reducing the levels of a range of bacteria, including *E. coli* under a set of specified conditions (e.g. at a particular temperature, dilution and contact time).
42. In order to ensure the adequate decontamination of surfaces, FBOs should ensure that they are using the appropriate disinfectant products by confirming with their suppliers that the products they are using meet, as a minimum, the specifications of these standards. This information may also be obtained from the label of the product, or by contacting the manufacturer directly.
43. It is essential that staff carrying out critical disinfection procedures fully understand instructions they are given for the storage and use of disinfectants and, where necessary, are provided with measuring containers or appropriately marked levels on the vessels used for making up dilutions. Food safety management procedures should not be considered capable of producing safe food where staff responsible for critical disinfection procedures cannot demonstrate how the dilutions are achieved to meet the business' work instructions. In addition, the design of work instructions must be capable of verifying that these will fulfil manufacturers' instructions.

Use of sanitisers

44. Sanitisers combine both cleaning and disinfection properties in a single product, usually as a spray. However, when used in a single stage process these products are **only** suitable as an interim 'clean-as-you-go' measure and never as a disinfection control for cross-contamination. Single stage use of a sanitiser is not sufficient to ensure thorough and effective disinfection to microbiologically safe standards in relation to controlling *E. coli* O157 cross-contamination.

45. Many FBOs prefer to purchase a single sanitising product rather than a separate detergent and disinfectant. In these cases a single sanitising product that meets the requirements of the BS EN 1276:1997 or the BS EN 13697:2001 can only be used to achieve the separate general cleaning and disinfection outcomes set out above, where the sanitiser is used in **both** stages of the cleaning and disinfection processes i.e. in general cleaning to provide a clean surface and then again to disinfect the surface.
46. As with disinfectants, the FBO must follow the manufacturer's instructions for dilution and contact time to ensure the sanitiser is effective.
47. Single use of a sanitiser is not sufficiently effective to ensure thorough disinfection to microbiologically safe standards. If a sanitiser is employed it must be used in both stages of the cleaning and disinfection process, i.e. in general cleaning to provide a clean surface and then again to disinfect the surface.
48. **Additional disinfection considerations for equipment and machinery, including vacuum packing machines:** The cleaning procedures described above are suitable for smooth impervious surfaces in good condition that can be fully inspected to ensure that they are visibly clean before they are disinfected. Although dual use of a complex machine for raw and ready-to-eat foods should never be considered safe, all food equipment should nevertheless be hygienically designed. Machinery supplied for use at work from 1995 should be CE marked to indicate that it was designed to comply with the European Machinery Directive⁴, which includes requirements for hygienic design. Detailed guidance on hygienic design requirements of the Machinery Directive can be found in BS EN 1672-2:2005+A1:2009 Food Processing Machinery Basic Concepts Part 2: Hygiene Requirements, BSI⁵.

⁴ Directive 2006/42/EC, and all previous versions

⁵ Additional requirements for some particular types of food machinery and packaging machinery are set out in more specific standards. Lists of type-specific standards for machinery can be found at:

[Hhttp://www.hse.gov.uk/food/standards.htm](http://www.hse.gov.uk/food/standards.htm)H for food machinery

[Hhttp://www.hse.gov.uk/food/cen.htm](http://www.hse.gov.uk/food/cen.htm)H for packaging machinery

Non-chemical disinfection – hot water and steam disinfection

49. The application of heat (thermal disinfection) is one of the most reliable ways of killing bacteria such as *E. coli* O157, but is not always practical, particularly in small food businesses. Where heat disinfection is being used, food businesses should ensure that the temperature and contact time is sufficient to destroy harmful bacteria. For instance, in certain non-retail establishments that require approval (such as meat cutting establishments), a water temperature of 82°C is legally required for the disinfection of tools.⁶ Steam cleaning can be effective for disinfecting the surfaces of certain types of machinery and equipment.
50. **Decontamination of utensils and small equipment:** Properly maintained commercial grade dishwashers in which water reservoirs are maintained at a temperature of more than 80°C providing contact times of at least 15 seconds offer adequate disinfection control. The manufacturer's cleaning and maintenance instructions must be followed and instructions typically include the removal of food debris, plastic wrapping and limescale from the water jets, filters and drains, as well as carrying out regular cleaning.
51. **Decontamination of cloths and mops used for cleaning:** Cleaning materials that were previously used for surfaces, equipment or utensils designated for preparation of raw foods should not subsequently be used for the cleaning of surfaces, equipment or utensils that are used for ready-to-eat foods, or in any designated clean area. Separate cloths must be designated for use only in clean environments (i.e. for cleaning surfaces and equipment used with ready-to-eat foods). In situations where cloths etc are to be re-used in clean areas, the laundering process should be regarded as critical to food safety. Laundering should be carried out at a suitably high temperature. A wash cycle that achieves 82°C or higher, can be considered acceptable. This may be achieved through a standard hot cycle, which typically operates at 90°C. Procedures, including contractual arrangements, must ensure that cycles employed for the washing of cleaning cloths are not changed to lower temperatures as a result of energy efficiency reviews.

⁶ Annex III, Section I, chapter II para 3 of Regulation (EC) No 853/2004

52. The use of disposable, single-use cloths provides a reliable way of ensuring cleaning and disinfection regimes do not present a cross-contamination risk.
53. In order to prevent the re-contamination of cleaning materials, it is imperative that all disinfectants are freshly prepared according to manufacturer's instructions prior to the disinfection of areas used to prepare ready-to-eat foods.

Personal hygiene and handling practices

Effective handwashing practice

54. All staff who work with food must be trained in effective handwashing procedures and ensure that they always wash their hands thoroughly.
55. Effective handwashing is always required prior to handling ready-to-eat foods in order to control cross-contamination. It **must** also occur after:
- going to the toilet
 - handling **any** food that may be a potential source of *E. coli* O157
 - hand contact with shared cash registers, door handles, light switches, aprons or other surfaces that could come into contact with staff handling raw foods
 - handling food and cleaning waste
 - eating
 - cleaning
56. Handwashing should form part of all food handlers working routine and FBOs should ensure all staff are trained in effective handwashing techniques. There must be an adequate supply of handwashing basins with hot water, soap and drying facilities available. Single-use towels or air driers are recommended for drying hands hygienically.

Effective handwashing takes time and requires effective technique

57. Effective handwashing must follow an appropriate technique. Handwashing techniques using soap and water, published by the Department of Health, the NHS, Health Protection Scotland, the Welsh Assembly Government or 'the Department of Health, Social Services and Public Safety Northern Ireland' in relation to infection control for health care workers should be sufficient. Although there may be slight variations, these techniques all include the following stages:
1. Wetting of hands prior to applying soap

2. A prescribed technique for hand rubbing, aimed at physically removing contamination from all parts of the hands
3. Rinsing
4. Hygienic drying

Best Practice:

For extra protection against cross-contamination it is recommended that a liquid hand wash that has disinfectant properties conforming to the European standards BS EN 1499:1997 is used. This information should be available on the label of the product, or may be obtained from the supplier or manufacturer.

58. Hands should not come into contact with taps after they have been washed. Clean single-use towels can be used to prevent contact with taps when turning them off, if taps are designed to be hand operable.

Best Practice:

Use of non-hand operable taps at handwashing facilities is recommended.

59. If, after washing, there is any remaining visible dirt on the skin it should be considered that the method has not been effectively applied and the process should be repeated.
60. It should be noted that hygienic hand rubs do not necessarily remove visible dirt and should **never** be used as a replacement for handwashing.

Best Practice:

HYGIENIC HAND RUBS

These products can provide an additional level of protection and are recommended following handwashing where there is an increased risk of cross-contamination e.g. when raw foods have been handled prior to handwashing.

Where hygienic hand rubs are being used, FBOs should ensure the products conform to standard BS EN 1500. Again, this information should be available on the label of the product, or may be obtained from the supplier or manufacturer.

Effective handwashing is essential to ensure adequate personal hygiene in all food operations.

Use of gloves and tongs for food handling

61. It is good practice to minimise hand contact with foods, particularly ready-to-eat foods, and many FBOs use gloves, tongs and other utensils to minimise direct hand contact.
62. Hands should always be washed thoroughly before putting gloves on and after taking them off. Gloves should be disposable and should always be changed between the handling of raw and ready-to-eat foods. Gloves should also be changed before handling ready-to-eat food if they have come into contact with any surfaces or objects not designated as clean (e.g. money), and also at every break and when gloves become damaged.
63. The use of separate packs of disposable gloves for different activities will assist with cross-contamination controls, providing care is taken to ensure that gloves are not contaminated by hands when they are being put on. Contaminated gloves must never enter a clean area used for handling or storage of ready-to-eat foods. Before entering a clean area, handwashing must take place before putting on clean gloves.
64. Tongs or other utensils can protect food from contamination but it is essential that equipment used to handle raw food is kept separate from that used for ready-to-eat food. Hand hygiene is also relevant where tongs are used in order to prevent the spread of contamination on handles.

Clothing and aprons

65. Cross-contamination can occur if food handlers handle both raw foods and ready-to-eat foods without adequate changing of clothes and aprons in between. Any contaminated outer clothing worn in a raw food preparation environment (e.g. aprons and overalls) should be changed before handling ready-to-eat foods or entering a clean area. Handwashing should take place after any change out of contaminated clothing and before putting on clean clothing. FBOs may consider using disposable aprons for different activities.

MANAGEMENT CONTROLS FOR *E. COLI* O157 CROSS-CONTAMINATION IN FOOD BUSINESSES

66. Effective food safety management controls are critical to controlling *E. coli* O157 cross-contamination hazards.
67. Food hygiene legislation requires food business operators to implement and monitor HACCP-based food safety management procedures⁷. It is not the intention of this guidance to explain those requirements in full, however, a number of the requirements are dealt with more fully in the following paragraphs.
68. FBOs should always ensure that technical controls are appropriately validated, that they are subject to ongoing monitoring, and their effectiveness verified through a system of own checks. Documented procedures should be up to date and cover all aspects of cross-contamination control.

Documented procedures and record keeping

69. Robust documented procedures are essential in ensuring that measures for controlling *E. coli* O157 cross-contamination hazards are being adhered to, and flexibilities available in some low risk situations should not apply to food control measures that fall within the scope of this guidance. Documented procedures are an essential record of the controls that must take place in an establishment to prevent cross-contamination and they will assist in training staff. Record keeping is essential in ensuring procedures for controlling *E. coli* O157 cross-contamination hazards are being adhered to.
70. Separation of areas, equipment and staff for handling ready-to-eat food should simplify procedures for control of cross-contamination. Readily identifiable utensils, cleaning equipments, protective clothing etc for use only in designated clean areas should simplify the monitoring of procedures. Use of a specific colour to identify such equipment and materials is commonly used in food businesses for this purpose. The level of monitoring and supervision must be sufficient to ensure complete adherence to critical safety controls.

⁷ Article 5 of Regulation (EC) No 852/2004.

71. Documented procedures should be based on sound evidence that the procedures are capable of controlling cross-contamination. This guidance document can be used to assist in determining types of control that should be effective if properly implemented. However, following the guidance will still require FBOs to ensure that disinfectants or sanitisers meet the specification recommended in this guidance and that machinery has been hygienically designed for its intended purpose and is being maintained, cleaned and disinfected according to manufacturers' instructions.
72. Procedures should be up to date and cover all aspects of cross-contamination control such as:
- methods of separation (e.g. designation of separate clean environments, identification of separate equipment)
 - cleaning procedures for surfaces and utensils, including dishwasher and washing machine temperatures, they should clearly detail the type of disinfection to be used along with the method of cleaning
 - details on the preparation and use of disinfectants and sanitisers
 - personal hygiene (e.g. handwashing requirements and use of protective clothing)
 - training and supervision of staff
 - arrangements for monitoring, verification checks, record keeping and corrective action

This list is not exhaustive and the nature of documentation will vary depending on the type of food operation. All records should be routinely checked and signed off by a competent member of staff.

Training and supervision

73. Food hygiene legislation requires that food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity. Training of applicable staff in the specific procedures required to control cross-contamination involving *E. coli* O157 will be crucial to effective cross-contamination control.
74. Effective handwashing technique, set out in this guidance is critical to cross-contamination prevention. Staff must know when handwashing is essential and how to do it properly. It is therefore critical that all relevant staff are

trained and verified as competent in handwashing technique before being deployed to work unsupervised in any safety-critical areas.

75. Similarly, the disinfection techniques set out in this guidance will require training of all staff that carry out safety-critical cleaning and disinfection. In particular, it is essential that staff are trained and verified as competent before being deployed to dilute and apply disinfectants, or to undertake hot water or steam disinfection.
76. Supervision of staff is required, as necessary, to ensure food is being safely prepared, where the food business operator cannot rely fully on training. This might be the case where staff are new to a particular duty.
77. Staff responsible for the development or maintenance of the HACCP-based food safety management procedures should have adequate training in the application of HACCP principles.

Verification and review

78. Food hygiene legislation requires food business operators to carry out verification checks to demonstrate that the documented procedures are working reliably. These checks are required in addition to routine monitoring and should be carried out whenever new or amended procedures are put in place. Particular attention should be paid to verification following maintenance work. Verification checks should also be carried out periodically at frequencies sufficient to show that all procedures are operating effectively.
79. FBOs should ensure that the measures applied to control cross-contamination are effective under all conditions of their business, and should not assume that the same procedures will be workable in all situations. The effectiveness of controls should be verified at each critical stage of the operation, during both quiet and busy periods, and particularly so when a new procedure is brought into service.
80. Environmental sampling can assist in verifying that procedures are being properly implemented. However, it is essential that the procedures themselves are demonstrated to be scientifically valid before they are employed as a critical cross-contamination control.
81. Any verification check that establishes loss of control should be considered seriously as a cross-contamination risk and acted on accordingly.

82. FBOs are required to review the procedures and make any necessary changes when there is any significant change to the operation of the premises or processes.

It is essential that FBOs can demonstrate procedures to implement valid technical controls described in this document and are able to provide evidence that these are being applied consistently in all relevant parts of the business.

Corrective action

83. The failure to follow any procedure essential to the control of *E. coli* O157 must always be regarded as a potentially serious incident.
84. Corrective action is always required following any failure in management control, or where a breakdown has been identified in procedures to prevent cross-contamination with *E. coli* O157.
85. In all cases where a critical cross-contamination control has been lost, the affected food preparation procedures should be stopped until control is re-established. In addition, the following actions must be taken:

a) Quarantine or disposal of affected product

All products potentially affected by a loss of control must be identified and placed under a system of control that will prevent its intended use as, or in, a ready-to-eat food. Action may range from placing the potentially contaminated food in adequately separated storage, with clear identification of its status (prior to reworking), to simply disposing of the potentially affected food.

b) Rework of affected product

In certain circumstances, and where it is practical to do so, it may be possible to subject the ready-to-eat food to further processing (e.g. heat treatment) that will eliminate *E. coli* O157. In such cases the affected product should be handled, stored and treated as a raw ingredient.

c) Product withdrawal and recall of affected product

Where a product does not meet food safety requirements, an FBO is required by law to organise withdrawal of the product through the supply

chain and to notify the appropriate local authority as well as the Food Standards Agency. Where any such product has been sold to consumers, the FBO must also ensure that appropriate information is disseminated to consumers to allow any remaining product to be recalled.

d) Re validation of procedures

Where a technical control has not been properly applied according to the operator's food safety management procedures, the FBO must reconsider the validity of the procedure. Where the FBO is unable to provide assurances that a particular fault will not occur in future, the current procedures cannot be considered to be valid and alternatives, including greater use of physical separation, must be considered.

Where there is a loss or a lack of critical cross-contamination control the operations affected should be stopped immediately until control is re-established.

FBOs should also consider whether quarantine, rework, disposal, withdrawal or recall of affected product is required to make sure potentially contaminated food is not supplied to consumers.

ENFORCEMENT ACTION

86. The scope of this guidance does not include advice to food law enforcing authorities on appropriate sanctions in the case of non-compliance with statutory requirements. However, the role of an enforcing authority is relevant to the overall framework of controls that may be required to protect consumers where an FBO has not implemented adequate controls or appropriate corrective actions.
87. Where the criteria set out in paragraphs 85 relating to corrective action, are found to apply, an enforcing authority must satisfy itself that all appropriate corrective actions are being put in place by the FBO. If there is ever any doubt that an FBO intends to fully implement appropriate corrective actions, the enforcing authority should actively intervene to ensure that any unsafe product is disposed of and, where necessary, withdrawn or recalled.
88. Enforcing authorities should always consider the exposure of ready-to-eat foods to the risk of *E. coli* O157 contamination as potentially constituting an imminent risk to consumers. Hygiene Emergency Prohibition Notices must therefore be considered where such controls are inadequate.
89. Food hygiene regulations in force throughout the UK provide powers for enforcing authorities to take possession of food for the purposes of destruction if it has not been produced, processed or distributed in accordance with statutory hygiene requirements.⁸

In circumstances where it is identified that critical cross-contamination controls are inadequate, enforcing authorities must intervene and take all appropriate action to protect public health where corrective actions have not been properly implemented by the FBO.

Enforcing authorities must always consider the use of Hygiene Emergency Prohibition Notices where inadequate control presents a risk of direct or indirect contamination of ready-to-eat foods by *E. coli* O157.

Enforcing authorities should take possession of food intended for use as a ready-to-eat product for the purposes of destruction if it has not been produced, processed or distributed in accordance with statutory hygiene requirements and it has been exposed to the risk of *E. coli* O157 contamination.

⁸ Food Hygiene (England) Regulations 2006 S.I. 2006/14 as amended
Food Hygiene (Scotland) Regulations 2006 S.S.I. 2006/3 as amended
Food Hygiene (Wales) Regulations 2006 S.I. 2006/31 (W.5) as amended
Food Hygiene Regulations (Northern Ireland) 2006 No. 3 as amended

ANNEXE 1: LEGAL REQUIREMENTS RELEVANT TO CONTROL OF CROSS-CONTAMINATION

Article 5 of Regulation (EC) No 853/2004 requires all food businesses (other than primary producers) to put in place, implement and maintain permanent procedures based on the HACCP principles set out in the table below. This table indicates the way in which this guidance links to the requirements of Article 5 that relate to cross-contamination and *E. coli* O157:

Article 5	Relevance to <i>E. coli</i> O157 cross-contamination.
(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels	This guidance is concerned with controls necessary when <i>E. coli</i> O157 is identified as a hazard that would present a risk to ready-to-eat foods without stringent precautions. Paragraphs 16 and 17 set out types of raw food where <i>E. coli</i> O157 should be assumed to be present but this does not lessen the obligation on food business operators to consider any other sources of <i>E. coli</i> O157 that could be present within an establishment.
(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels	This guidance stipulates that full control of cross-contamination will require separation of sources of contamination from any route by which ready-to-eat foods could be exposed to risk of contamination.
(c) establishing critical limits at critical control points that separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards	There is no acceptable critical limit for <i>E. coli</i> O157 contamination in ready-to-eat food due to its low infective dose and the serious and untreatable illness that it can produce. Separation as set out above, is required to reliably achieve acceptable control of cross-contamination.
(d) establishing and implementing effective monitoring procedures at critical	Monitoring procedures must be capable of ensuring that separation procedures are rigorously implemented. Paragraphs

control points	<p>65 to 77 provide guidance on monitoring and supervision.</p> <p>In any circumstances where disinfection or handwashing is required as a prerequisite hygiene measure or as part of the control measures in an establishment, procedures must be monitored sufficiently to ensure that they are rigorously implemented and effective (see paragraphs 54-60). This must ensure that cleaning and disinfection and handwashing are applied at all junctures set out in the operator's procedures using the correct technique, appropriate dilutions and adequate contact times.</p>
(e) establishing corrective actions when monitoring indicates that a critical control point is not under control	<p>Failure to follow any procedure essential to the control of <i>E. coli</i> O157 must always be regarded as a potentially serious incident. Corrective action is always required following any failure in management control, or where a breakdown has been identified in procedures to prevent cross-contamination with <i>E. coli</i> O157. Paragraphs 82 to 84 in this document provide additional guidance on corrective action.</p> <p>In all cases where a critical cross-contamination control has been lost, the affected food preparation procedures should be stopped until control is re-established. In addition, corrective action must ensure that any products potentially at risk are not placed on the market.</p>
(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and (g) establishing documents and records	<p>Verification includes initial validation of procedures that are intended to be used. This guidance provides a framework that accepts separation as a valid control measure. It also provides a framework</p>

<p>commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).</p> <p>When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.</p>	<p>within which food business operators can develop valid procedures:</p> <ul style="list-style-type: none"> • for the selection and use of disinfectants by reference to European standards and manufacturers' instructions • for effective handwashing technique by reference to existing guidance for health care workers <p>However, the guidance should not be interpreted as accepting the use of disinfection or handwashing as a critical control where separation is physically possible.</p> <p>Paragraphs 77 to 81 in this document provide further advice on periodic checks to verify that the validated procedures are working effectively.</p>
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90. In addition to Article 5, there are certain specific provisions of Regulation (EC) No 852/2004 that are particularly relevant to the control of cross-contamination risks in food premises. The table below provides further guidance on these requirements:

CHAPTER I General requirements for food premises	Relevance to <i>E. coli</i> O157 cross-contamination.
<p>1. Food premises are to be kept clean and maintained in good repair and condition.</p> <p>2. The layout, design, construction, siting and size of food premises are to:</p> <p>(a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise airborne contamination, and provide adequate working space to allow</p>	<p>The size and design of premises must be sufficient to allow good practices in relation to contamination protection. Size of premises should therefore not prevent separation as a necessary practice to protect food against any type of cross-contamination, including protection from <i>E. coli</i> O157.</p>

<p>for the hygienic performance of all operations</p> <p>(b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces</p> <p>(c) permit good food hygiene practices, including protection against contamination and, in particular, pest control</p>	
<p>CHAPTER II Specific requirements in rooms where foodstuffs are prepared, treated or processed</p>	
<p>1. In rooms where food is prepared, treated or processed...the design and layout are to permit good food hygiene practices, including protection against contamination between and during operations.</p>	<p>The design and layout of food rooms must be sufficient to allow good practices in relation to contamination protection during all operations. The layout of food rooms should therefore not prevent separation as a necessary practice to protect food against any type of cross-contamination, including protection from <i>E. coli</i> O157.</p>
<p>CHAPTER VIII Personal hygiene</p>	
<p>1. Every person working in a food-handling area is to maintain a high degree of personal cleanliness and is to wear suitable, clean and, where necessary, protective clothing.</p>	<p>Personal hygiene requirements apply to every person working in a food handling area (not only to food handlers). The required standard for personal cleanliness is 'high' and must be a higher standard than merely adequate. This means that handwashing must be effective at removing <i>E. coli</i> O157. Any contaminated outer clothing worn in a raw food preparation environment (e.g. aprons and overalls) should be changed before handling ready-to-eat foods or entering a clean area.</p>
<p>Annex II, CHAPTER IX:</p>	

Provisions applicable to foodstuffs	
<p>2. Raw materials and all ingredients stored in a food business are to be kept in appropriate conditions designed to prevent harmful deterioration and protect them from contamination.</p> <p>3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state.</p>	<p>All ready-to-eat foods or ingredients must be protected at all times from <i>E. coli</i> O157 contamination by any possible route. Controls must ensure full protection of clean areas for ready-to-eat foods against any general spread of <i>E. coli</i> O157 contamination.</p>
CHAPTER X Provisions applicable to the wrapping and packaging of foodstuffs.	
<p>1. Material used for wrapping and packaging are not to be a source of contamination.</p> <p>2. Wrapping materials are to be stored in such a manner that they are not exposed to a risk of contamination.</p>	<p>Adequate separation is required to ensure that contaminated wrapping materials cannot lead to either direct contamination of food or indirect contamination of clean areas where contamination could subsequently contaminate food.</p>
CHAPTER XII Training	
<p>Food business operators are to ensure:</p> <p>1. That food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity</p>	<p>This guidance provides more detail on areas where training will be critical to ensure that the cleaning and disinfection of surfaces and the washing of hands is effective. The outcome of training, instruction and/or supervision must provide complete assurance that these procedures are carried out on every occasion required and strictly in accordance with the procedures established by the food business operator.</p>

91. Regulation (EC) No 178/2002 prohibits the sale of unsafe food and requires every food business operator to initiate a withdrawal of any food supplied by the business if he believes it is unsafe.

FOOD SAFETY OFFICIAL CONTROLS DELIVERY

Report by Alison Gleadle, Director of Food Safety

1 SUMMARY

- 1.1 The Food Standards Agency is the UK's central competent authority (CCA) for official controls on food safety. These controls are currently delivered through a variety of means: FSA employees; other Government Departments; contractors; and (mostly) local authorities. These delivery responsibilities vary across the four countries of the UK. This range of responsibility for food safety brings complexity. The FSA, as the UK's competent authority, wishes to consider how best to secure efficiency, consistency, resilience and sustainability in this essential public health protection function.
- 1.2 The Board is asked to:
- Note the evidence that supports the need to review the current food safety delivery regime;
 - Agree that the Executive should review the current delivery model and compare it to an alternative delivery model that involves four national bodies; and
 - Agree to consider the results of the review and proposals for action at its open meeting in July 2011.

2 INTRODUCTION

- 2.1 The FSA is the CCA responsible for official controls on food safety in the UK. The current delivery model of these official controls is extremely complex, multi-tiered and involves many different groups. It is further complicated by the fact that delivery responsibilities are different across the four countries of the UK. **Annex A** summarises the division of responsibilities for all food and feed official controls, including those for which other government departments are the CCA. For those brave enough, the complexity is described in even greater detail in **Annex B**.
- 2.2 As the competent authority the FSA is responsible to protecting the interests of consumers in relation to food. To do this it needs a system that ensures food business operators are able to fulfil their obligations for safe food production. In the current climate of increased financial pressures it is timely to consider how best to secure efficiency, consistency, resilience and sustainability in this fundamental public health protection function.
- 2.3 Other Governments in the UK have started to question the current delivery regime. The Board will recall that in August 2010, the First Minister for Wales

asked the FSA to review food law enforcement in Wales. He asked if consumers in Wales are adequately protected and asked for an evaluation of other possible models of delivering food law enforcement. The interim report to the First Minister is attached to this paper at **Annex C – INFO 11/01/01**. The final report will be submitted to the First Minister by the end of February 2011.

3 STRATEGIC AIMS

- 3.1 This work goes to the heart of the FSA's statutory purpose of protecting public health from risks which may arise in the consumption of food, including risks caused by the way it is produced or supplied.
- 3.2 It would directly address current Outcome 5: "Regulation is effective, risk-based and proportionate, is clear about the responsibilities of food business operators, and protects consumers and their interest from fraud and other risks.", and support the proposed Outcome "Enforcement is efficient, consistent, risk-based and proportionate and is focused on improving public health."

4 DISCUSSION

- 4.1 The FSA's core principles for the delivery of official controls are:
- Most effort on interventions of greatest impact on consumer protection,
 - Controls across the UK should be coherent and consistent,
 - Should be clear accountability for delivery of official controls,
 - Efficiency should be maximized, and
 - Stakeholders should know who is responsible for what.
- 4.2 The complexity of the current model makes it extremely difficult to achieve these core principles, particularly in securing delivery on a consistent and coherent basis.
- 4.3 In the UK, 434 local authorities, employing nearly 2,900 highly qualified, professional enforcement officers and over 600 administrative staff, at a cost of £190 million are responsible for ensuring food safety compliance in over 560,000 premises. These are made up of approximately 400,000 catering and restaurant businesses; 130,000 retailers; and 16,000 food manufacturers and others.
- 4.4 The UK food sector is one of the most sophisticated and developed in the world. The current official control delivery arrangements do not mirror the modern food supply chain, which operates across LA boundaries. Food businesses range from multi-nationals and global brands to artisan owner/producers. The turnover of food businesses in the UK can be over 20 per cent each year in metropolitan areas.

- 4.5 Local authorities carry out over ½ million on-site food hygiene and standards checks each year, with the highest risk businesses likely to receive more frequent visits. Local authorities take over 150,000 enforcement actions annually. These are primarily written warning letters, but also more formal interventions.
- 4.6 Despite these resources and interventions:
- Persistent non-compliance is high in some parts of the food chain. As many as 24 per cent of all takeaways were non compliant at two consecutive inspections;
 - The rate that standards improve varies by business type. 66 per cent of non-compliant supermarkets had improved by the next inspection, compared to just 35 per cent of takeaways; and
 - Overall compliance and therefore consumer protection is not improving over time. Across all food businesses: for every one that improves, another declines.
- 4.7 **Annex D** contains information about current delivery of official controls by LAs from available data, commenting further on overall resourcing, performance and resilience. Key issues relate to:
- staffing levels: 2008/09 data confirms that 8% of positions allocated for official control delivery within LAs remain unfilled; and
 - considerable variance in enforcement action taken: just under a quarter of LAs took no action against establishments falling below the broad compliance level; approximately 7% of all food premises remain unrated; and 6% of risk categories A, B and C had overdue interventions.
- 4.8 The first of the FSA's core principles references consumer protection. Official controls must deliver consumer protection and secure public health benefits. However, given the complexity in terms of inputs and the responsibilities of a wide range of contributors it is not possible to validate the role official control delivery has in securing those benefits. We therefore work on the basis of food business operator compliance as a proxy for effective official controls outcomes (mainly in relation to food hygiene). This is discussed further in **Annex E**.
- 4.9 **Financial pressures.** Local Authorities are facing an unprecedented cut in their funding. Spending cuts currently suggested go way beyond the conventional efficiency drives often seen in the past. LAs will have to make hard decisions as to whether functions are reduced or are even to continue. This view is shared by the Local Government Association, the Front Line First Task Force and the Chartered Institute of Public Finance and Accountancy (CIPFA). All are

concerned that LAs will have to consider all options with no preconditions to protect or provide services. These concerns are shared across the UK.

- 4.10 Although the full extent of the financial settlement for LAs is not yet fully understood, it is clear that in addition to an immediate reduction in Local Government spending of 2 per cent, the Revenue Support Grant will be incrementally reduced over four financial years between 2010 – 11 and 2014 -15, amounting to a real term reduction in Local Government spending of 28 per cent.
- 4.11 Forthcoming financial constraints are therefore unlikely to improve current resourcing and performance of LAs. This presents significant risk to the Agency in terms of its responsibilities as the central competent authority.
- 4.12 **Others' views:** others are also starting to question the current delivery model. In addition to the First Minister for Wales' review, Professor Hugh Pennington questioned the delivery regime in his review of the 2005 *E.coli* outbreak in Wales, and most recently Lord Young questioned the delivery regime in his report *Common Sense, Common Safety*. The report and recommendations were subsequently endorsed in their entirety by the Coalition Government Cabinet.
- 4.13 The architecture to support local authorities in England and Wales in their regulatory work is diminishing, with stringent cutbacks made to Local Government Regulation (LGR) and the Local Better Regulation Office (LBRO) being absorbed in the Department for Business, Innovation and Skills.
- 4.14 The European Commission through its Food and Veterinary Office (FVO) has often expressed concern about the complexity of the UK's delivery model. FVO missions frequently identified failings around process and record keeping of approved premises.
- 4.15 **Would a different model work? It might.** Building on the experience of setting up the Meat Hygiene Service (**Annex F**), and learning from that process, an alternative model might be one that is more centralised, but for practical (and political) purposes is based on national boundaries. This would be a model of centralised control and delivery in each of the countries of the UK.
- 4.16 It is clearly difficult to evidence the benefits for a system that does not exist. However, centralising official controls delivery within the meat sector clearly improved levels of compliance, consistency and performance management. And it aligns to a number of the key principles for official controls delivery at 4.1 above.
- 4.17 For the rest, the initial experience with the creation of Operations Group in 2010, which has brought together previously disparate responsibilities and given them new focus on delivery of the FSA's public health commitments, has demonstrated the scope for:

- Greater ability to focus resources and interventions throughout the UK on impacts that would have the greatest impact on consumer protection;
- Improved performance management and CCA role delivery;
- Clearer accountability for delivery of official controls throughout the food chain; and
- Greater efficiencies and response to the financial pressures arising out of the 2010 Comprehensive Spending Review.

3.18 Outsourcing the entire function to the private sector is not an option because of legislative constraints. Regulation 882/2004¹ sets out the characteristics, obligations and functions of competent authorities, as well as the basis upon which performance of those functions is audited by the FVO. It specifies the circumstances under which specific tasks can be delegated to control bodies². This does not include actions taken in the case of non-compliance. This means that the competent authority, which is defined as the central authority of a member state and not a private entity, must retain responsibility for dealing with non-compliance.

5 IMPACT

- 5.1 Undertaking a review will require input from delivery partners, other government departments, food businesses and consumers.
- 5.2 The review will need to be properly resourced and managed within FSA.

6 CONSULTATION

- 6.1 At the Future Food Hygiene Conference on 3 December 2010, the opportunity was taken to announce our intention to undertake a review of official controls delivery. This was supplemented by letters to key stakeholders, explaining that Board agreement to this would be sought in January.
- 6.2 The review will seek evidence and comment from a wide range of stakeholders across the UK.

7 RESOURCE IMPLICATIONS

- 7.1 The review will be undertaken as a managed project, by a dedicated team in the Food Safety Group, drawing on contributions from across the FSA, and involving

¹ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (as amended).

² “‘control body’ means an independent third party to which the competent authority has delegated certain control tasks.” Article 2(5) of Regulation (EC) No 882/2004.

external stakeholders.

8 LEGAL IMPLICATIONS

- 8.1 The review and proposals for action will need to consider the extent to which the FSA is fulfilling its obligations as a Central Competent Authority and gains assurance from those to whom competence is delegated. It will also be necessary to consider the implications of the Food Standards Act 1999 which created the FSA.

9 RISK IMPLICATIONS

- 9.1 Undertaking a review informed by evidence from stakeholders will minimize the risk that the analysis and proposals for action presented subsequently to the Board are ill-founded and would be unlikely to address the issues and shortcomings identified.

10 SUSTAINABILITY ISSUES

- 10.1 By undertaking a review, the Executive will be able to consider and evaluate the full range of potential impacts – environmental, social and economic - in relation to food safety official controls delivery models.

11 CONCLUSION AND RECOMMENDATION

- 11.1 There is a growing body of evidence that the current complex and inconsistent delivery model, coupled with declining resources at LA level and uncertainty about good performance being sustained or poor performance improving amongst food businesses, that the current model does not give the FSA, as the central competent authority, evidence or assurance that delivery is effective.
- 11.2 It is now right and timely to undertake a review of the current delivery model and explore and develop an alternative delivery model that is more nationally consistent and involves four national bodies.
- 11.3 The Board is asked:
- Note the evidence that supports the need to review the current food safety delivery regime;
 - Agree that the Executive should review the current delivery model and compare it to an alternative delivery model that involves four national bodies; and
 - Agree to consider the results of the review and proposals for action at its open meeting in July 2011.

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